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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,439	12/05/2003	Scott A. Burton	59405US002	9418
32692	7590	11/03/2005	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			RONESI, VICKEY M	
			ART UNIT	PAPER NUMBER
			1714	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/728,439		BURTON ET AL.	
	Examiner		Art Unit	
	Vickey Ronesi		1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) 61, 67-69, 89, 90, 92 and 93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60, 62-66, 70-88 and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/12/05, 6/2/05, 6/14/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-59, 62-66, 70-72, and 75-88) in the reply filed on 8/22/2005 is acknowledged. Upon reconsideration, the examiner has added "medical article" claims 60, 73, 74, 89, and 91 to Group I and are examined below. Claims are 61, 67-69, 89, 90, 92, and 93 are withdrawn.

The examiner has also reconsidered the election of species requirement and it is therefore withdrawn. Therefore, all hydrophilic polymer species have been examined.

Claim Objections

2. Claims 3, 8, 14, 17, 36, and 57 are objected to because of the following reasons:

With respect to claims 3, 8, 14, "polysaccarides" is misspelled and should read as "polysaccharides".

With respect to claim 17, "metal oxide" in lines 1-2 of the claim has antecedent basis and should read as "the metal oxide".

With respect to claims 36 and 57, not all of the listed polymers are elastomeric, e.g., polyether-block-amide and ester of (meth)acrylic acid.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-6, 11, 13-49, 51-58, 62-66, and 73-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1, 19, 22-24, 27, 30-32, 62, 66, and 75, the term "substantially" in is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

With respect to claim 1, the list "a metal oxide of silver, copper, zinc, and combinations thereof" causes confusion since it is not made clear if "metal oxide" only applied to silver or to copper and zinc, too.

With respect to claim 2, if an alternative expression is intended, the word "and" should be replaced with "or" or proper Markush language should be recited. Otherwise, the claim is interpreted as mandatorily comprising all of the hydrophilic polymer recited.

With respect to claim 11, "the hydrophilic polymer composition" lacks antecedent basis.

With respect to claim 13, "the metal oxide particle size" lacks antecedent basis.

With respect to claims 36 and 57, "a (C1-C20) acrylic ester of meth(acrylic) acid" is not a compound. If applicant intended this to read as "a (C1-C20) alkyl acrylic ester", such is not supported by the specification as originally filed.

With respect to claims 46 and 47, a composition does not have a structure and therefore cannot be in the form of a film or a foam.

With respect to claims 51-56, the term "the hydrophobic material" lacks antecedent basis.

With respect to claim 73 and 74, the term "The medical article" lacks antecedent basis.

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With respect to the remaining claims, they are rejected for being dependent on a rejected claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, 7, 8, 13-15, 62, 70, 75-77, 84, and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Bao et al (CN 1308102, abstract).

A full English-language translation has been ordered. Only the abstract has been relied upon in the following rejection.

Bao et al discloses a process of preparing nanometer-sized (80-100 nm) silver oxide comprising dissolving silver nitrate in water, then adding ammonia water, then adding sodium hydroxide and a protecting agent (e.g., polyvinyl-pyrrolidone or polyvinyl alcohol, i.e., hydrophilic polymer). Before the solution is washed and vacuum dried to obtain the silver oxide, the ingredients in solution read on the presently claimed composition.

In light of the above, it is clear that Bao et al anticipates the presently cited claims.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al (CN 1308102, abstract).

The discussion with respect to Bao et al in paragraph 4 above is incorporated here by reference.

While the abstract of Bao et al fails to disclose the presently claimed mixing order, it is the examiner's position that the mixing order is obvious, absent a showing of criticality for the mixing order. Case law holds that the selection of any order of mixing ingredients is *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930).

6. Claims 1-4, 6-9, 11, 12, 19-39, 42-45, 48, 49, 50, 52, 53, 55-60, 75, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152).

Asmus discloses a composite (col. 40, lines 16-45) used in wound care (col. 44, lines 17-30) comprising 1-95 wt % a gel having a size of 1-600 microns (col. 19, lines 16-20) containing hydrocolloid (i.e., hydrophilic polymer) (col. 6, line 54 to col. 8, line 50) and a swelling agent; antimicrobial agents such as silver oxide (col. 12, lines 27-44); pressure sensitive adhesive (i.e.,

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matrix polymer) (col. 4, lines 53 to col. 6, line 29); water (col. 9, line 66-67); and other additives (col. 6, lines 3-4; col. 12, lines 50-68).

With respect to claims 7-9, 11, 12, 19-23, 26-31, 34-39, 42-45, 52, 53, and 55-59, these claims are product-by-process claim and therefore “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, while the presently cited claims recite that a hydroxide source, is added to convert the metal compound into a metal oxide, given that Asmus discloses the use of silver oxide, the final composition of Asmus and that presently claimed is not different.

With respect to the particle size of absorbent (i.e., gel) particle in a nonhydrated form, given that the swelled gel has a particle size of 1 micron and that the weight ratio of hydrocolloid:swelling agent is (col. 40, lines 32-33), it is intrinsic that in an unswelled state the gel particles have a particle size less than 1 micron.

With respect to the utilize of secondary absorbent particles, it is the examiner's position that it is obvious to utilize more than one ingredient that does the same thing. It is well settled that it is prima facie obvious to combine two ingredients, each of which is targeted by the prior art to be useful for the same purpose. *In re Lindner* 457 F,2d 506,509, 173 USPQ 356, 359 (CCPA 1972).

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With respect to the water solubility of the bioactive compound, given that the microbial agents of Asmus are like those presently claimed, the microbial agents intrinsically have a solubility in water of at least 0.1 gram per liter in water.

Asmus fails to disclose the particle size of the antimicrobial agent such as silver oxide.

While Asmus does not disclose the particle size of the antimicrobial agent, it is the examiner's position that the size are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in Laurin et al which teaches that the size of antimicrobial agent (col. 3, lines 1-8) is critical in controlling the delivery time and tissue irritation considerations, wherein submicron sizes are preferred (col. 4, lines 50-68).

In view of this, it would have been obvious to one of ordinary skill in the art to utilize appropriate sizes of the antibacterial agent, including those within the scope of the present claims, so as to produce desired end results and thereby arrive at the presently cited claims.

7. Claims 5, 10, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152) and further in view of Ahmed et al (US 6,458,877).

The discussion with respect to Asmus and Laurin et al in paragraph 6 above is incorporated here by reference.

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Asmus does not disclose the use of a hydrocolloid that it is a quarternary ammonium salt of an organic polymer.

Ahmed et al, like Asmus, discloses superabsorbent polymers (i.e., hydrocolloids) and teaches that quarternary ammonium salts of an organic polymer is a common hydrocolloid (col. 11, line 67).

Given that Asmus is open to the use of any suitable hydrocolloid material, it would have been obvious to utilize an ammonium salt as taught by Ahmed et al and thereby arrive at the presently cited claims.

8. Claims 13-18, 84-87, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152) and further in view of Yan et al (US 2003/0185889).

The discussion with respect to Asmus and Laurin et al in paragraph 6 above is incorporated here by reference.

Neither Asmus nor Laurin et al discloses the use of an ammonia source in its composition.

Yan et al teaches that in order to increase the solubility of silver oxide in water, the use of ammonia water is needed (paragraph 0029).

Given that the silver oxide in Asmus is utilized in a water, it would have been obvious to one of ordinary skill in the art to utilize ammonia or any of its derivative salts to increase the solubility of silver oxide as taught by Yan et al. Furthermore, it is the examiner's position that the mixing order of the hydrophilic polymer the ammonia source, and metal oxide is obvious.

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Case law holds that the selection of any order of mixing ingredients is *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930).

9. Claims 62, 64-66, 70, 72-74, 76-78, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152) and further in view of Bao et al (CN 1308102, abstract).

The discussion with respect to Asmus and Laurin et al in paragraph 6 above is incorporated here by reference.

Asmus teaches that the antimicrobial agents are combined with the gel before after the polymerization of the hydrocolloid (i.e., hydrophilic polymer) (col. 12, lines 27-36). Note that the composition is coated (i.e., molded) onto a substrate and that the hydrocolloid is subject to radiation (col. 15, lines 55-56).

While Asmus and Laurin et al disclose the use of silver oxide and silver salts as antibacterial agent, they do not teach the use of a hydroxide source.

Bao et al teaches that submicron silver oxide as obtained by the combining a silver salt (e.g., silver nitrate) with sodium hydroxide (i.e., hydroxide source).

Given that Asmus teaches the use of silver oxide and further given that silver oxide is obtained through the combination of a silver salt and a hydroxide source, it would have been obvious to one of ordinary skill in the art to obtain the silver oxide of Asmus by the method taught by Bao et al and thereby arrive at the presently cited claims. Furthermore, it is the examiner's position that the mixing order of the hydrophilic polymer the hydroxide source, and

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metal compound is obvious. Case law holds that the selection of any order of mixing ingredients is *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930).

10. Claim 79 rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152) and further in view of Bao et al (CN 1308102, abstract) and Ahmed et al (US 6,458,877).

The discussion with respect to Asmus, Laurin et al, and Bao et al in paragraph 9 above is incorporated here by reference.

Asmus does not disclose the use of a hydrocolloid that it is a quarternary ammonium salt of an organic polymer.

Ahmed et al, like Asmus, discloses superabsorbent polymers (i.e., hydrocolloids) and teaches that quarternary ammonium salts of an organic polymer is a common hydrocolloid (col. 11, line 67).

Given that Asmus is open to the use of any suitable hydrocolloid material, it would have been obvious to utilize an ammonium salt as taught by Ahmed et al and thereby arrive at the presently cited claim.

11. Claims 63 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152) and further in view of Bao et al (CN 1308102, abstract) and Antelman (US 6,436,420).

The discussion with respect to Asmus, Laurin et al, and Bao et al in paragraph 9 above is incorporated here by reference.

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None of Asmus, Laurin, or Bao et al disclose the use of an oxidizing agent to increase the valence state of the silver.

Antelman teaches that higher valence silver compounds obtained by oxidizing agents exhibits enhanced microbial properties (abstract, col. 1, line 67).

Given that Asmus discloses the use of antimicrobial agents such as silver, it would have been obvious to one of ordinary skill in the art to enhance the antimicrobial properties with the use of an oxidizing agent as taught by Antelman and thereby arrive at the presently cited claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-12, 19-60, 75, and 89 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 19-21, 27-39, 41-46, 49, 51, 53-63, and 70 of copending Application No. 10/728,577 (published as US 2004/0180093) alone or in view of Laurin et al (US 4,603,152).

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US appl. '577 claims a polymer composition and a method of making the composition and medical articles thereof, wherein the composition comprises a bioactive agent, absorbent hydrophilic microparticles, and an organic polymer matrix.

The claims of US appl. '577 are silent with respect to the particle size of the bioactive agent or metal oxides as the bioactive agent.

While US appl. '577 does not disclose the particle size of the bioactive agent, it is the examiner's position that the size are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in Laurin et al which teaches that the size of a bioactive agent (col. 3, lines 1-8) is critical in controlling the delivery time and tissue irritation considerations, wherein submicron sizes are preferred (col. 4, lines 50-68).

In view of this, it would have been obvious to one of ordinary skill in the art to utilize appropriate sizes of the bioactive agent, including those within the scope of the present claims, so as to produce desired end results and thereby arrive at the presently cited claims.

This is a provisional obviousness-type double patenting rejection.

13. Claims 1-12, 19-60, 75, and 89 are directed to an invention not patentably distinct from claims 1-15, 19-21, 27-39, 41-46, 49, 51, 53-63, and 70 of commonly assigned copending Application No. 10/728,577 (published as US 2004/0180093). Specifically, see the discussion set forth in paragraph 12 above.

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The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned copending Application No. 10/728,577 (published as US 2004/0180093), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Contact Information

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickey Ronesi whose telephone number is (571) 272-2701. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/31/2005

vr




VASU JAGANNATHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700